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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,168	03/12/2004	Michael Spiegel	LDP-8080 CIP	1047

7590 02/07/2007  
Michael Spiegel  
199 Palm Avenue  
Miami, FL 33139

EXAMINER
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HOPKINS, CHRISTINE D

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/801,168

Applicant(s)

SPIEGEL, MICHAEL

Examiner

Christine D. Hopkins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,9,12-18,21,22,24 and 26 is/are rejected.
- 7) ☒ Claim(s) 5,7,8,10,11,19,20,23,25 and 27-30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. This Office Action is responsive to the Amendment filed 6 November 2006. Claims 1-30 are now pending. The Examiner acknowledges the amendments to claims 1 and 9, as well as the addition of claims 15-30.

### ***Oath/Declaration***

2. The instant application contains a power of attorney filed on 05 September 2006. Said power of attorney appears to cite two distinct customer numbers for the power of attorney and the correspondence address. However, neither of the cited customer numbers appears associated with attorney Loren Donald Pearson. Accordingly, the Office action is being mailed to you as the inventor.

Applicant may, of course, file a new power of attorney in the application to have a registered attorney or agent represent you before the Office. In the absence of an attorney or agent of record, all amendments and other papers filed in the application must be signed: (1) by you; or (2) if there is an assignee of record of an undivided part interest, by you and such assignee; or (3) if there is an assignee of the entire interest, by such assignee; or (4) by a registered patent attorney or agent, not of record, who acts in a representative capacity under the provisions of 37 CFR 1.34.

***Claim Objections***

3. Claims 5-8 are objected to because of the following informalities: at line 3 of claim 5, line 2 of claim 6, and line 2 of claim 7, " $\lambda$ " should be changed to --time constant ( $\lambda$ )--; and at line 2 of claim 8, --Insulated Gate Bipolar Transistor (IGBT)-- should replace "IGBT." Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding the limitation "when said coil is 5 cm from the tissue," no such support is found in the specification.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Regarding the limitation of inducing "an electric field in the tissue

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exceeding 1 mV/cm," the instant specification provides that an electric field greater than 10 mV/cm is needed to establish effective charge transport and thus produce a therapeutic result (pg. 24, lines 17-23).

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Litovitz (U.S. Patent No. 5,968,527). Litovitz teaches the application of a time-varying magnetic field for the purpose of repairing damaged tissue. Regarding claim 1, Litovitz discloses the application of an electric field greater than 1mV/cm when the frequency is in the range of 15 to 100 Hz (col. 8, lines 23-35). The particular use of an electric field within this range is also suggested in the instant application (pg. 34, lines 10-16). Furthermore, Litovitz teaches, as is known, that the increase of the electric field requires an increase in the frequency, thus a 10 mV/cm electric field is capable of being applied (col. 8, lines 25-30), in accordance with claim 15. Regarding claim 2, Litovitz further teaches the use of sinusoidal waveforms, and in view of the frequency range taught by both Litovitz and the instant application, Litovitz anticipates, and is capable of, a saw-tooth shaped magnetic field. In view of claim 14, the coil as taught by Litovitz is

capable of producing an asymmetric waveform as discussed above in reference to the "saw-tooth shaped" field.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Litovitz (U.S. Patent No. 5,968,527) in view of Dissing et al. (U.S. Patent No. 6,561,968). Litovitz discloses the invention as claimed, see rejection supra; however Litovitz does not explicitly teach a duration of the growth and decay phases of the field. Dissing et al. (hereinafter Dissing) teaches the use of a time-varying magnetic field that will induce an electric field in an organism for promoting growth. Regarding claim 3, the time-varying magnetic field disclosed by Dissing has a growth phase being at least ten times a duration of its decay phase (see Fig. 7). Furthermore, Dissing teaches the use of a frequency (1-100 Hz) comparable to that of Litovitz and the instant application (col. 12, lines 6-28 of Dissing). Regarding claim 4, Dissing teaches emitters capable of withstanding current switching in the coil via an output switch, to be interpreted as first and second subcircuits. A pulse of +50V (growth phase) is imposed followed by -50V (decay phase) for creating a rapidly changing magnetic field (col. 12, lines 39-64). A rate constant of 63% ( $\lambda$  no greater than 1) is determined by an increase in current (L/R)

and has been determined by Dissing to be essential for creating a therapeutic effect (col. 11, lines 61-67). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have varied the duration of the magnetic field as taught by Dissing to a time-varying magnetic field as disclosed by Litovitz in order to induce an electromotive force on charged particles in tissue that is of therapeutic benefit.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Litovitz (U.S. Patent No. 5,968,527) in view of Manni (U.S. Patent No. 2,939,976). Litovitz discloses the invention as claimed, see rejection supra; however Litovitz does not disclose a coil configured to receive a current exceeding 2000 volts. Manni discloses high voltage coils in the range of 1500 V to 2500 V (col. 4, lines 59-62). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to employ the high voltage coil of Manni to the invention of Litovitz for accommodating large voltages necessary to reverse the electric field quickly and efficiently.

12. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Litovitz (U.S. Patent No. 5,968,527) in view of Day et al. (U.S. Patent No. 7,088,210). Litovitz discloses the invention as claimed, see rejection supra; however Litovitz does not disclose a coil that is liquid cooled. Day et al. (hereinafter Day) teach an apparatus for cooling a magnet. With respect to claims 12 and 13, Day discloses a cylindrical coil **34** (see Fig. 5) enclosed within an electromagnet **10** and inner housing **14** whereby a fluid may enter to cool the coil (col. 6, lines 65-67 and col. 7, lines 1-11). Therefore, at the time of the invention it would have been obvious to one of ordinary skill

in the art to have adapted the cooling system of Day to the coil of Litovitz in an effort to cool the coil which receives a high voltage load.

13. Claims 16-18, 21-22, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dissing (U.S. Patent No. 6,561,968). Dissing teaches the use of a time-varying magnetic field that will induce an electric field via a coil in an organism for promoting growth. Dissing further teaches the increase of the magnetic field in the coil to invoke an electric field in a first direction, followed by a rapid decline in the magnetic field providing current flow in the tissue of an opposing direction (col. 13, lines 58-67 - col. 13, lines 1-5) resulting in different growth and decay times as evident in Fig. 7, wherein the time for increasing the field is greater than that of the rapid decay phase. Furthermore, Dissing discloses the use of a frequency (1-100 Hz) comparable to that of Litovitz and the instant application (col. 12, lines 6-28 of Dissing). Dissing does not expressly disclose the use of an apparatus taught by Litovitz, however Dissing discloses an apparatus similar to that (comparable range of frequencies as discussed above) for creating therapeutic charge transfer in the tissue of a patient via a coil placed near the tissue of a patient within a few centimeters having an electromotoric force of 0.025 mV (col. 14, lines 47-54 and Fig. 4). Further regarding claim 26, since Applicant fails to teach the amount of charge being transferred in either direction of the tissue, the increasing and decreasing of the magnetic field creating movement in opposing directions as taught by Dissing is capable of controlling the amount of charge moved.

Since the instant application fails to teach the particular use of such an apparatus with the method as claimed, and merely recites "providing" such an apparatus short of



any limitation which may patentably distinguish the use of such an apparatus with the method over any method of the prior art, at the time the invention was made, it would have been an obvious matter of design choice to one having ordinary skill in the art to have incorporated an apparatus such as that disclosed by Litovitz to a method as suggested by Dissing for creating beneficial, therapeutic charge transfer in an individual subjected to an electric field. Therefore, it would have been prima facie obvious to modify Litovitz to obtain the invention as specified in claims 16-18, 21-22, 24 and 26 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Dissing.

#### ***Allowable Subject Matter***

14. Claims 5, 7-8, 10-11, 19-20, 23, 25, and 27-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claims 5 and 7, the prior art of record teaches  $\lambda$ , or a time constant no greater than 1, in a circuit, however it fails to teach a time constant of a first circuit at least ten times greater than that of an additional circuit which aids in creating a rapidly changing magnetic field that induces a therapeutic effect on tissue. Furthermore, the prior art of record, in accordance with claim 8, incorporates the use of an output switch, however it fails to teach the use of an IGBT switch capable of supporting the high voltage applied to the coil of the instant application.

In view of claims 10-11 and 25, while the prior art of record teaches a duty cycle of ten and eighty percent, the prior art only teaches one magnetic field superimposed on a system for interrupting external electromagnetic signals deemed detrimental to the system. Furthermore, an electric field induced at such a duty cycle is imperative to achieving charge transport in tissue of the patient.

Regarding claims 19-20, while the prior art of record teaches the increase and decrease of a magnetic field having a saw-tooth shape, it teaches a field having a non-linear shape, and not linear as supported by the instant claims such that a therapeutic charge is more effectively induced. The prior art of record further teaches the increase of a magnetic field for invoking an electric charge transfer in tissue, however it does not explicitly disclose such a small increase in intensity as disclosed in the language of claim 23.

In view of claims 27-30, the prior art of record teaches the use of multiple circuits for efficiently increasing and decreasing the amount of current available to a coil, however the prior art fails to teach or suggest the interconnection of the increasing and decreasing subcircuits with an IGBT for switching between the two and supporting such a large voltage supplied to the coil of the instant application.

### ***Response to Arguments***

15. Applicant's arguments filed 6 November 2006 with respect to the rejection of claims 2 and 14 under 35 U.S.C. 101 have been fully considered and are persuasive. The rejection of claims 2 and 14 has been withdrawn.

16. Applicant's arguments filed 6 November 2006 with respect to the rejection of claims 1-3 and 14 under 35 U.S.C. 102(e) citing Canedo (2003/0171640) as being unavailable as prior art considering Applicant's claim of benefit to copending U.S. Application 10/035,854 filed 9 November 2001, have been fully considered and are persuasive. Applicant further contends that support for each limitation of the rejected claims is found in the original specification. However, this argument is not persuasive. Regarding the limitation "when said coil is 5 cm from the tissue" at line 4 of claim 1, Applicant points to page 25 of the specification of U.S. Application 10/035,854. No such support is found regarding inducing an electric field in tissue exceeding 1 mV/cm, when a coil is 5 cm from tissue on page 25 of the specification, nor is it found anywhere else within the specification of the instant application upon further review.

Applicant's arguments that Canedo further fails to teach an output electrical field of 1mV/cm as recited in the language of claim 1 are moot in view of new grounds of rejection made in view of a newly found prior art reference to Litovitz ('527) which teaches the induction of an electric field in tissue via a time-varying magnetic field as claimed.

Additionally, whereas Applicant has amended claim 1 to recite an apparatus for creating therapeutic charge transfer by inducing an electric field in tissue exceeding 1 mV/cm, it is noted that page 24 of the specification of the instant application at lines 17-23 states that the generation of an induced electric field greater than 10 mV/cm is

needed to establish the effective transport of charge necessary to produce a therapeutic result.

Regarding claim 3, Applicant's arguments are moot in view of the new grounds of rejection citing Litovitz ('527) in view of Dissing et al. ('968).

17. Applicant's arguments filed 6 November 2006 with respect to the rejection of claims 4-7 under 35 U.S.C. 103(a) citing Canedo ('640) in view of Tysb ('400) and further in view of Kurtz ('922) are moot in view of the new grounds of rejection citing Litovitz ('527) in view of Dissing et al. ('968) for claims 4 and 6. However, Applicant's arguments with respect to claims 5 and 7 have been fully considered and are persuasive. The rejection of claims 5 and 7 has been withdrawn.

18. Applicant's arguments filed 6 November 2006 with respect to the rejection of claim 8 under 35 U.S.C. 103(a) citing Canedo ('640) in view of Tysb ('400) and further in view of Kurtz ('922) in view of Mangano ('768) have been fully considered and are persuasive. The rejection of claim 8 has been withdrawn.

19. Applicant's arguments filed 6 November 2006 with respect to the rejection of claim 9 under 35 U.S.C. 103(a) citing Canedo ('640) in view of Manni ('976) are moot in view of the new grounds of rejection citing Litovitz ('527) in view of Manni ('976).

20. Applicant's arguments filed 6 November 2006 with respect to the rejection of claims 10-11 under 35 U.S.C. 103(a) citing Canedo ('640) in view of Litovitz ('665) have been fully considered and are persuasive. The rejection of claims 10-11 has been withdrawn.

21. Applicant's arguments filed 6 November 2006 with respect to the rejection of claims 12-13 under 35 U.S.C. 103(a) citing Canedo ('640) in view of Day ('210) are moot in view of the new grounds of rejection citing Litovitz ('527) in view of Day ('210).

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Christine D Hopkins  
Examiner  
Art Unit 3735

Charles A. Marmor, II  
Supervisory Patent Examiner  
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